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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,104	01/27/2004	Woonza M. Rhee	2500-2287.05	2188

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
01/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,104	RHEE ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of IDS, request for extension of time, request for continued examination under 37 CFR 1.1141, amendments and remarks, all filed 10/16/07. Claims 19, 20, 23, 24, 53, 54, 57 and 58 are amended. New claims 69-81 are added. Claims 1-81 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/16/07 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is scope of enablement.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Level of ordinary skill in the art.

See below:

1) Nature of the invention.

The nature of the invention is methods of augmenting human skin fibroblast within the mammalian body, comprising a) providing a first crosslinkable component having m nucleophilic groups, wherein $m > 2$;

(b) providing a second crosslinkable component having n electrophilic groups capable of reaction with the m nucleophilic groups to form covalent bonds, wherein $n > 2$ and $m + n > 5$;

(c) applying the first and second crosslinkable components to the tissue; and

(d) allowing the first and second crosslinkable components to crosslink in situ,

wherein the first and second crosslinkable components are biocompatible, synthetic, and nonimmunogenic. As stated, however, claim 1 recites that any or a wide representation of soft and hard tissue is capable of being treated by the above method.

2) State of the prior art and the predictability or lack thereof in the art.

Discovering a candidate drug for such a broad use involves repeating the same test for several screening of a hundreds to several million times. This requires a great deal of reproducibility from the test. In order to obtain the state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which compounds or composition or formulation exhibited the desired pharmacological activities (i.e. what compounds can treat which specific disease on the soft or hard tissue). The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher,* 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. Further, their mode of action is often unknown or very unpredictable and administration of the drugs can be accompanied by undesirable side effects.

Thus, in the absence of a showing of correlation between augmenting varying types of both soft and hard tissue claimed as capable of being treated by the method of the instant claims, one of ordinary skill in the art is unable to fully predict possible results from the administration of the compounds due to the unpredictability of the role of the disease.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is undue experimentation as mentioned above. One of ordinary skill in the art would first need to determine the type of soft and hard tissue to be treated.

7) Breadth of claims.

Claims 1-68 are extremely broad due to the vast number of possible augmentation of soft .and hard tissue encompassed by the instant invention.

Therefore, in view of the some of the Wands factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compounds encompassed in instant claims, with no assurance of success.

5. The above list is by no means complete, but demonstrates the extraordinary breadth of causes, mechanisms, and treatment (or lack thereof) for soft and hard tissue. It establishes that it is not reasonable for one of skill in the art to perfom the necessary augumentation within the mammalin body without undue experimentation

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. There is no description in the specification for each m and $n > 5$

The greater than 2 or greater than 3 for m and n is open ended. The specification supports m + n to be 5 and support is not found for greater that 2 or 3 that is open ended. Thus, for example, claims employing m at a value of say 5 and greater is neither described nor exemplified. The specification does not inform the public of the limits of the monopoly asserted. Similarly, claims employing n at a value of say 5 and greater is neither described nor exemplified. The expression provided in the specification paragraph [0034] represents only an

invitation to experiment regarding the possible m and n for the cross-linkable components claimed in the instant application.

Response to Arguments

6. Applicant's arguments filed 1/29/07 have been fully considered but they are not persuasive.

Applicant argues that the language of the claims is identical to the language of the claim 1 in US 6,534,591 wit respect to first and second cross-linking composition and that under 35 USC 282, a patent shall be presumed valid so that since the claims of the patent were used, the examined claims should also be enabled.

Response:

Patentability of the examined claims is not based on the issued claims of 6,534,591 and each application is examined on its merits and not examined and allowed because claims of parent application are allowed.

7. Claims 1-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to product and the product is defined with functional language alone without identifying what the compounds are, it is thus unclear as to what the limitation might be.

It is further unclear what applicant means by "augmenting soft or hard tissue" as recited in claim 1.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-81 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rhee et al. (US 5,162,430) or Rhee et al. (US 5,308,889, herein after identified as Rhee '889).

10. Rhee repairs tissues such as nose, ear, knee, larynx, tracheal rings; or replace tendon, ligament and blood vessel tissue by applying a mixture of collagen and dPEG (column 12, lines 49-61). Collagen meets the limitation of multi-electrophilic polymer in which succinimidyl groups are the electrophilic group and the dPEG is the nucleophile. While Rhee does not specifically state that the two solutions are separately applied, the two solutions are mixed and applied and polymerization and cross-linked in situ. In the alternate, giving the general teaching of Rhee in which the polymerization is rapid (column 12, lines 43 and 44), one of ordinary skill in the art at the time the invention was made would have reasonable expectation of success to repair and support tissue requiring some degree of structure by applying the individual compositions to the desired tissue where the two composition rapidly polymerize.

11. Rhee ('889) augments tissue by forming strings comprising collagen-polymer conjugates (column 4, lines 60-64; claims 12-16). Collagen meets the limitation of multi-electrophilic polymer in which succinimidyl groups. Rhee lists many polymer that the reference refers to as preferred (column 6, line 67; column 7, lines 1-56) and of these mono-functional and

multifunction PEG are named (column 7, line 31 to column 8, line 54). See also columns 14-24. In the alternate, giving the general teaching of Rhee '889, one of ordinary skill in the art at the time the invention was made would have reasonable expectation of success to augment soft tissue by administering the individual composition to the tissue site requiring augmentation in order for the two compositions to advantageously polymerize at the sites.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
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